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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/068,804	05/14/98	MILLER	S 00786/292002

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HM22/0508

EXAMINER

BASKAR, P

ART UNIT	PAPER NUMBER
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1645

21

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/068,804

Applicant(s)

MILLER, SAMUEL I.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18 and 46-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 46-86 and 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Response to Amendment

1. The amendment filed on 2/20/01 has been entered into the record. Claim 17 has been amended. Claims 46-86 and 17-18 are pending in the application.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

3. Examiner has withdrawn 35 U.S.C. 112, second paragraph rejections for claims 46, 52, 58, 64, 70, 76 and 82.
4. In view of applicants submission of evidence "Exhibit A", Examiner has withdrawn rejection of claims 46-86 and 17-18 under 35 U.S.C. 102 (a) as anticipated by Hueck et al 1995 (Mol. Biol 18: 479-490).

Rejections Maintained

5. Rejection of claims 46-86 and 17-18 under 35 U.S.C 112, first paragraph is maintained as set forth in the previous office action (Paper NO # 18).

Applicants arguments filed on 2/20/2001 have been fully considered but they are not found persuasive.

Applicant states that the applicant does not understand the Examiner's question about cDNA etc. Applicant clarifies with the examiner that the bacterial genes do not include introns. However, the instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated DNA molecules

a) comprising SEQ ID NOS: 1, 2, 3, 4, 13, 10 and 15.

b) comprising a nucleic acid encoding a polypeptide comprising the amino acid of SEQ ID NOS: 5, 6, 7, 8, 14, and 12

c) which hybridizes under conditions of hybridization to a nucleic acid molecule consisting of the nucleotide sequence ID NOS: 1, 2, 3, 4, 13, 10 and 15. The claims are further drawn to vectors comprising the above sequences and host cells transfected with them.

The specification discloses an isolated cDNA sequence, SEQ ID NO: 1-4, 13 and 10 which encodes a predictive polypeptide sequence, SEQ ID NO. 5-8, 14 and 12 respectively. Absent evidence to the contrary, each of the SEQ ID NOS elected for examination is deemed to be an incomplete cDNA. Because the cDNAs that correspond to the SEQ ID NOS mentioned in

the claims are not full-length, a sequence prepared from undefined parts of a cDNA clone will not comprise the entire coding region of any particular gene, nor is it clear the partial sequence is even in frame to encode a polypeptide. The claims, as written, however, encompass polynucleotides, which vary substantially in length and also in nucleotide composition. The broadly claimed genus additionally, encompasses *Salmonella typhimurium* genes, as well as genes incorporating only portions of the disclosed sequence.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the gene. The art indicates that the structures of genes with naturally occurring regulatory elements and untranslated regions is empirically determined (Harris et al. *J. of The Am Society of Nephrology* 6:1125-33, 1995; Ahn et al. *Nature Genetics* 3(4): 283-91, 1993; and Cawthon et al. *Genomics* 9(3): 446-60, 1991). Therefore, the structure of these elements is not conventional in the art and skilled in the art would therefore

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not recognize from the disclosure that applicant was in possession of the genus of nucleic acid, including genes, comprising SEQ ID NO: 1-8, 10, 12-15.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

6. Rejection of claims 46-86 under 35 U.S.C. 102 (a) as anticipated by WO 95/02048 is maintained for the same reasons as set forth in the previous office action.

Office regrets the oversight made in the rejection in paper no 18 as 102 (e) instead of 102 (a).

Applicant argues that the claims are drawn to SspB, SspC, SspD and SspA and nucleic acid molecules encoding these proteins. The prior art does not disclose specific nucleotide or amino acid sequences related to any of related to ~~any of these~~ genes. Examiner cited this prior art because the claims as recited broadly could read on DNA of S.typhi which contain SspB, SspC, SspD and SspA genes. Examiner has cited prgH gene, as an example to show that the bacterial cell with virulence attenuated mutation (prgH) comprises the nucleic acid molecules (SspB, SspC, SspD and SspA) as recited in the claims. *Wider*

In the absence of evidence to the contrary the disclosed prior art bacterial cell comprises the nucleic acid molecules (SspB, SspC, SspD and SspA) as recited in the claims. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Rejection of claims 46-86 and 17-18 under 35 U.S.C. 102 (a) as anticipated by Hermant et al 1995 (Mol. Biol 17:781-789) is maintained as set forth in the previous office action.

Applicant's submission of evidence "Exhibit D " is not sufficient to overcome the rejection because the reference was made available to the public (October 3, 1995) before the filing date of the priority application (November 14, 1995). The submitted evidence "Exhibit ^(S) ~~D~~ declaration contain conclusionary statements without sufficient evidentiary support. Therefore, the declaration is insufficient to obviate the rejection. Evidentiary support may include copies of pertinent lab note book entries, the other co-authors in the reference cited are working under the supervision of the inventor and they are not the inventors of the present claimed invention and

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submission of the sequences claimed to any established data bases prior to the prior art dates by the inventor himself.

8. ~~In view of applicant's submission of evidence "Exhibit B and C" Examiner has withdrawn~~ Rejection of claims 46-86 and 17-18 under 35 U.S.C. 102 (a) as anticipated by Kaniga et al 1995 (J. Bact 177:3965-3971) is maintained as set forth in the previous office action.

Applicant's submission of evidence "Exhibit ~~B~~" is not sufficient to over come the rejection because the reference was made available to the public (July 8, 1995) before the filing date of the priority application (November 14, 1995). The submitted evidence "Exhibit ~~A~~" declaration contain conclusionary statements without sufficient evidentiary support. Therefore, the declaration is insufficient to obviate the rejection. Evidentiary support may include copies of pertinent lab note book entries, the other co-authors in the reference cited are working under the supervision of the inventor and they are not the inventors of the present claimed invention and submission of the sequences claimed to any established data bases prior to the prior art dates by the inventor himself.

Applicant states that the Examiner has not explained how SipB and SipC can anticipate the SspB and SspC. Examiner in paper No 11 explained that the Sip B and SipC are analogous to SspB and SspC and without the presence of nucleic acid molecules, the amino acids will not be secreted as anticipated by Kaniga et al. Finally Kaniga et al discloses invasion of S.typhimurium in to epithelial cells. S.typhimurium comprise s all the nucleotide sequences which encode SspA, SspD, SspB, and Sspc.

Status of Claims

9. No claims are allowed.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

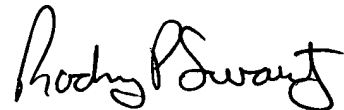
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/1/01

A handwritten signature in black ink, appearing to read 'Padma Baskar', with a long, sweeping horizontal line extending to the right.A handwritten signature in black ink, appearing to read 'Rodney P. Swartz', with a stylized, cursive script.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER